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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,671	06/12/2006	Walther Jary	4662-193	5006
23117 7590 03/28/2008 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203				
EXAMINER				
ZUCKER, PAUL A				
ART UNIT		PAPER NUMBER		
1621				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/582,671

Applicant(s)

JARY ET AL.

Examiner

Paul A. Zucker

Art Unit

1621

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/20/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-10 and 12-18 is/are rejected.
- 7) ☒ Claim(s) 5, 6 and 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-856)
- _____ Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- _____ Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-18, drawn to an improved method for preparing chiral or enantiomer-enriched beta-amino acids, aldehydes, ketones or gamma-amino alcohols.

Group II, claim 19, drawn to an intermediate for pharmaceutical products.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The products of Boesten et al (US 2003/0097005 05-2003, see below) anticipate the compound claim 19 which cannot have the special technical feature required for unity of invention.

1. Amended claim 19 is directed to an invention that is independent or distinct from the invention originally claimed for the reasons set forth above.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for

prosecution on the merits. Accordingly, claim 19 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

NOTE: A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Current Status

2. This action is responsive to Applicants' amendment of 20 December 2007.
3. Receipt and entry of Applicants' amendment is acknowledged.
4. Claims 1-19 are pending.
5. The rejection under 35 USC § 101 set forth in paragraph 1 of the previous Office Action mailed 20 June 2007 is withdrawn in response to Applicants' amendment.
6. The rejections under 35 USC § 112, second paragraph, set forth in paragraphs 1 - 2 of the previous Office Action mailed 20 June 2007 is withdrawn in response to Applicants' amendment.
7. The rejection under 35 USC § 102 set forth in paragraph 5 of the previous Office Action mailed 20 June 2007 is withdrawn in response to Applicants' amendment.
8. Claims 1-4, 7-10 and 12-18 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Boesten et al (US 2003/0097005 05-2003) in view of Bailey (Chemical Reviews, The Reactions of Ozone with Organic Compounds, 1958, 58(5), pages 925-1010).

Instantly claimed is a process for the successive ozonolysis of compounds of formula (I) followed by either reduction or oxidation.

Boesten teaches (Paragraphs [0083]-[0088]) the ozonolysis of (R)-phenylglycine Amide-(R)-isopropylhomoallylamine. The reaction is either carried out under oxidative (NaOH/MeOH) conditions (with autogenous oxygen or ozonide at room temperature (25°C)) to give the methyl ester or followed by reduction to the alcohol with and then a water quench using at least 1-2 equivalents based on NaBH_4 followed by aqueous extraction and chromatography.

The differences between the processes taught by Boesten and those instantly claimed are that:

- a. Boesten teaches reaction at -78°C while temperatures of reaction between -40°C to $+30^\circ\text{C}$ are instantly claimed;
- b. Boesten teaches oxidation to form the ester while oxidation to form the acid is instantly claimed; and,
- c. Boesten teaches only reduction with NaBH_4 to form the alcohol while reduction with agents such as hydrogen/catalyst combinations are instantly claimed.

Bailey teaches (Page 986, 1st 3 paragraphs) the use of a variety of solvents including acetic acid at temperatures of between -25°C to $+25^\circ\text{C}$. Bailey teaches (Page 989, Table 7) the oxidation of a large variety of substrates to the carboxylic

Art Unit: 1621

acid in the presence of oxidizing agents such as O_2 or H_2O_2 . Baily teaches (Page 991, Table 8, entries 1 and 4) the catalytic reduction to produce aldehydes.

Thus one of ordinary skill in the art would have been motivated to modify the processes of Boesten according to the teachings of Bailey in order to extend the utility of Boesten's processes to other product classes and optimize yields. There would have been a reasonable expectation for success based upon the generality of Bailey's teaching.

Thus the instantly claimed process would have been obvious to one of ordinary skill in the art.

Examiner's Response to Applicants' Remarks With Regard to This Rejection

9. Applicants have presented argument with regard to this rejection. The Examiner responds to these below:

- a. Applicants' argue that the Examiner's rationale for the above rejection appears to be flawed since Boesten is directed to the ozonolysis of amide allylamines and that the homoallylamine that is subjected to ozonolysis is (R)-phenylglycine amide-(R)-isopropylhomoallylamine. The Examiner notes, however, that Applicants formula encompasses compounds in which R6 is an N-protective group which includes amides as a class. In further support of this position, the Examiner directs Applicants' attention to Examples 4-11 on pages 13-17 of the instant specification where such "amide allylamines" are subjected to ozonolysis.

- b. Applicants argue that R5 cannot be an amino group and therefore, Applicants argue, formula (I) cannot embrace the amide allylamines of Boeston. To this the Examiner responds:
 - i. Compounds in which R5 is an NH_2 group are *vinyl amines* and not allyl amines as argued by Applicants. Regardless of nomenclature, however, such substitution is not at issue in the present case;
 - ii. Compounds in which R6 is a substituted carbonyl group are encompassed by formula (I) and correspond to the homoallylamine exemplified by Boeston as set forth in the rejection of record above.
- c. Applicants argue that one of ordinary skill in the art would not substitute the non-amide allylamines defined in the application in the Boeston process to arrive at the instantly claimed invention. In response, The Examiner points out that no "substitution" is required, since, as demonstrated above, the homoallylamine of Boeston is encompassed by the "allylamines" of instant formula (I).

Applicant's arguments filed 20 December 2007 have been fully considered but they are not persuasive for the reasons set forth above

10. Claims 5, 6 and 11 are finally objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

11. Claims 1-19 are pending. Claims 1-4, 7-10 and 12-18 are finally rejected. Claims 5, 6 and 11 are finally objected to. Claim 19 is withdrawn from consideration as being directed to a non-elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Evonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 1621

/Paul A. Zucker/
Primary Examiner,
Art Unit 1621